



FEB 28 2005

James F. Haley, Jr.
1251 Avenue of the Americas
New York NY 10020-1104Re: Patent Term Extension
Application for
U.S. Patent No. 5,258,494

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,258,494, which claims the medical device OP-1® Implant, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,525 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 1,525 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of April 2, 2003 (68 Fed. Reg. 16062). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (3485 - 720) + 142 \\ &= 1,525 \text{ days}\end{aligned}$$

Since the regulatory review period began November 14, 1991 before the patent issued (November 2, 1993), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From November 14, 1991 to November 2, 1993 is 720 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the 14 year limit of 35 U.S.C. § 156(c)(3) nor the limitations of 35 U.S.C. § 156(g)(6) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,258,494
Granted:	November 2, 1993
Original Expiration Date ¹ :	November 2, 2010
Applicant:	Hermann Oppermann, et al.

¹Subject to the provisions of 35 U.S.C. § 41(b).

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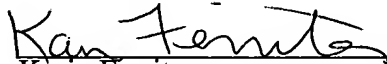
Owner of Record: Stryker Corporation
Title: Osteogenic Proteins
Classification: 530/326
Product Trade Name: OP-1® IMPLANT
Term Extended: 1525 days
Expiration Date of Extension: January 5, 2015

Any correspondence with respect to this matter should be addressed as follows:

By mail: Commissioner for Patents
Mail Stop Patent Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX: (571) 273-7744
Attn: Office of Patent Legal Administration

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7744.


Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857
Attention: Claudia Grillo

RE: OP-1 Implant

FDA Docket No. : 02E-0147